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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,341	04/14/2004	Gary W. Guenst	P0010073.00	5392

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EXAMINER	
TYSON, MELANIE RUANO	
ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
04/27/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/824,341	GUENST, GARY W.	
	Examiner	Art Unit	
	MELANIE TYSON	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-14,17-20,32-37 and 39-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-14,17-20,32-37, and 40-43* is/are rejected.

7)☒ Claim(s) *8 and 39* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the applicant's amendment received 19 April 2010. The application is not in condition for allowance for the reasons set forth below. Claims 7, 15, 16, 21-31, and 38 remain cancelled.

Response to Arguments

Applicant's arguments with respect to claims 1-6, 8-14, 17-20, 32-37, and 39-43 have been considered but are moot in view of the new ground(s) of rejection. Applicant's arguments filed 19 April 2009, with respect to the rejection(s) of claim(s) 1-6, 8-14, 17-20, 32-37, and 39-43 over Gifford and Hattler have been fully considered and are persuasive. Therefore, the FINAL rejection necessitated by the amendment received 12 November 2009 has been withdrawn and a new FINAL rejection is set forth below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 43 is rejected under 35 U.S.C. 102(e) as being anticipated by Gifford, III et al. (U.S. Patent No. 5,695,504). Gifford discloses a method of joining a blood conduit to a blood vessel (see entire document) comprising the steps of making an

incision (700) in the blood vessel wall (682), inserting a tubular member (691) into the conduit (graft vessel 254), advancing the tubular member distal region (693) through the incision, performing the anastomosis (or "fixedly joining the conduit distal region to the vessel wall") near the incision while providing an oxygenated liquid flow from an outlet (694) of the tubular member disposed within the conduit and into the blood vessel by way of an inlet end or by providing fluid through the tubular member from the conduit proximal region (for example, see paragraph 250), and after performing the anastomosis (or "fixedly joining the conduit to the vessel") withdrawing, or retracting, the tubular member through the conduit (for example, see column 65, line 58 through column 66, line 22, and Figure 54 for further details), wherein blood flow is enabled through the entire length of the conduit once the anastomosis has been completed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 9-14, 17, 32-37, and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gifford, III et al. (U.S. Patent No. 5,695,504) and Taylor et al. (U.S. Patent No. 5,925,054). Gifford discloses a method of joining a blood conduit to a blood vessel (see entire document) comprising the steps of making an incision (700) in the blood vessel wall (682), inserting a tubular member (691) into a conduit (graft vessel 254), advancing the tubular member distal region (693) through the incision, expanding the tubular member distal region (the inflatable balloons 696 and 697) radially outward, performing the anastomosis (or "fixedly joining the conduit distal region to the vessel wall") near the incision while providing an oxygenated liquid flow from an outlet (694) of the tubular member disposed within the conduit and into the blood vessel by way of an inlet end or by providing fluid through the tubular member from the conduit proximal region (for example, see paragraph 250), and after performing the anastomosis (or "fixedly joining the conduit to the vessel") withdrawing, or retracting, the tubular member through the conduit (for example, see column 65, line 58 through column 66, line 22, and Figure 54 for further details), wherein blood flow is enabled through the entire length of the conduit once the anastomosis has been completed.

Gifford also discloses the anastomosis can be performed using any of the methods described in the disclosure, in which Gifford discloses anastomosis procedures that may include suturing the conduit to the vessel wall (for example, either the use of sutured anastomosis or stapled anastomosis techniques is described in column 68, lines 6-14). Gifford further discloses the blood vessel may be a coronary artery, the aorta, or any other vessel (for example, see column 9, lines 32-34), the conduit may be

a saphenous vein or an internal mammary artery (for example, see column 66, line 64 through column 67, line 7), the oxygenated fluid may include blood or a non-blood oxygenated carrying substance (for example, see column 66, lines 8-13), and the blood oxygenated fluid may include blood supplied from the patient's femoral artery (for example, in the procedure in which the blood vessel is the femoral artery) or aorta (for example, in the procedure in which the blood vessel is the aorta). Gifford fails to disclose the step of expanding the lumen of the tubular member distal region radially outward.

Taylor discloses a method of providing oxygenated fluid flow through a vessel during an anastomosis (see entire document). Taylor teaches the step of expanding a distal region of a tubular member inserted in the blood vessel, including its lumen, radially outward in the blood vessel in order to provide enhanced contact with the interior wall of the vessel to maximize isolation of the anastomosis site (for example, see column 10, line 41 through column 11, line 12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form Gifford's tubular member distal region as taught by Taylor and perform the method step of also expanding the lumen of the tubular member, since such a modification would have yielded predictable results, namely, a method of effectively isolating the anastomosis site during an anastomosis procedure.

With further respect to claims 3 and 34, Gifford discloses inserting a tubular member into a conduit and advancing a tubular member through a vessel, wherein the inserting is performed before the advancing. The applicant has not disclosed that

performing the inserting after advancing provides an advantage, is used for a particular purpose, or solves a stated problem over inserting before advancing. Furthermore, the applicant discloses that the inserting step may be performed either before or after the advancing step. It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the inserting after the advancing as a matter of design choice, since it appears both steps would perform equally well and a mere reversal of these steps involves only routine skill in the art.

With further respect to claims 14 and 42, Gifford discloses that if the blood flow through the tubular member is insufficient, oxygenated fluid may be injected through a luer fitting connected to the tubular member (for example, see column 66, lines 8-13). One of ordinary skill in the art would recognize that insufficient blood flow may be related to an insufficient, or low, blood pressure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to inject the fluid through the tubular member at a pressure higher than the patient's blood pressure in a procedure in which blood flow through the tubular member is insufficient. Doing so would ensure the fluid passes through the tubular member and into the blood vessel.

With further respect to claim 17, it would have been obvious to one having ordinary skill in the art at the time the invention was made to inject the fluid pressure by a bulb through a port into the tubular member that is distinct from the proximal end as a matter of design choice, since the applicant has failed to disclose such a configuration provides an advantage, is used for a particular purpose, or solves a stated problem, and

it appears injecting the fluid through a port in the proximal end (as disclosed by Gifford) would perform equally well.

With further respect to claim 32, Gifford discloses that end-to-end anastomosis procedures are well known and suggests that the device disclosed is suitable for both end-to-side and end-to-end anastomosis procedures (for example, see background of the invention). To perform the steps of advancing the tubular member through the blood vessel proximal end and fixedly joining the conduit distal region to the vessel wall near the blood vessel proximal end would have been obvious to one having ordinary skill in the art at the time the invention was made if the procedure required an end-to-end anastomosis be performed.

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gifford, III et al. and Taylor et al. as applied to claim 1 above, and further in view of Amor et al. (U.S. Patent No. 6,059,809). Gifford as modified by Taylor discloses the claimed invention except for the step of inserting a stiffening member within the tubular member. Amor discloses a method (see entire document) comprising the steps of inserting a tubular member (4) through a conduit (8) and into a vessel. Amor teaches inserting a stiffening member (6) within the tubular member (4) in order to serve as a guide through the vessel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to insert a stiffening member within the tubular member of Gifford as modified by Taylor. Doing so would provide a means for guiding the tubular member through the vessel, thus preventing inadvertent damage to the blood vessel wall by the tubular member.

Allowable Subject Matter

Claims 8 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims (I.e., if claim 8 were incorporated into claim 1 and claim 39 were incorporated into claim 32, claims 1-6, 9-14, 17-20, 32-37, and 40-42 would be in condition for allowance).

Conclusion

Applicant's amendment received 12 November 2009 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE TYSON whose telephone number is

(571)272-9062. The examiner can normally be reached on Monday through Friday 7-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
April 21, 2010

/Darwin P. Erezo/
Primary Examiner, Art Unit 3773